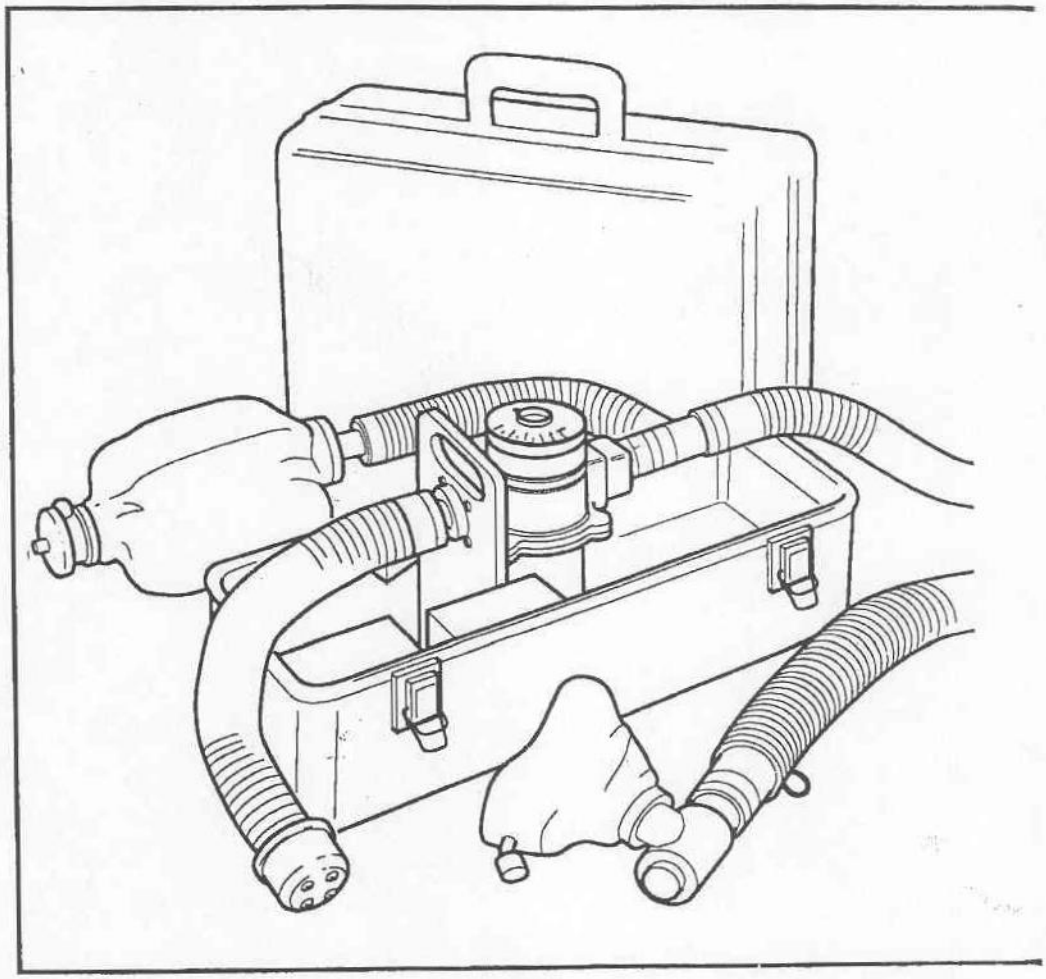
Ohmeda

Ohmeda Universal PAC

Operation And Maintenance Manual



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Contents

		Page
1.0	**Introduction**	1
1.1	Operation And Maintenance Manual	1
1.2	Precautions	1
1.3	User Responsibility	1
1.4	Servicing Policy	2
2.0	**Description**	3
3.0	**Specification**	4
4.0	**Principle Of Operation**	5
4.1	Description	5
4.2	Duration Of Use	5
5.0	**Performance**	6
5.1	Performance Curves	6
5.2	Nominal Performance With Other Agents	8
5.3	Effect Of Temperature On Performance	8
5.4	Effects Of variables	11
	A Temperature	11
	B Pressure	11
	C Back Pressure	11
6.0	**Checks Before Use**	12
6.1	Visual Checks	12
6.2	Leak Tests - Internal	12
6.3	Leak Tests - External	12
7.0	**Operation**	13
8.0	**Operating Instructions**	14
8.1	General	14
8.2	Filling And Draining	15
	A Filling	15
	B Draining	15
	C Packing	15
	D Cleaning	16
	E Changing To A Specific Agent	16
8.3	Minimum Alveolar Concentration (M.A.C.) ...	17
9.0	**Factors Relating To Individual Anesthetics**	17
9.1	General	17
9.2	Isoflurane	17
9.3	Halothane	17
9.4	Diethylether	17
9.5	Enflurane	18

Contents

		Page
10.0	**Servicing**	18
10.1	General	18
10.2	Scope	19

Illustrations

Fig. 1	PAC Portable Anesthesia System	4
Fig. 2	PAC Portable Anesthesia System - Schematic	5
Fig. 3	Halothane And Isoflurane Performance Curve	6
Fig. 4	Diethylether Performance Curve	7
Fig. 5	Enflurane Performance Curve	7
Fig. 6	Effect Of Temperature On Performance - Halothane And Isoflurane	9
Fig. 7	Effect Of Temperature On Performance - Diethylether	9
Fig. 8	Effect Of Temperature On Performance - Enflurane	10
Fig. 9	Draw-over Vaporizer Schematic	13
Fig.10	Filling And Draining	15
Fig.11	Changing The Control Dial	16

Tables

Table 1	Nominal Performance With Other Agents ...	8
Table 2	Minimum Alveolar Concentration (M.A.C.)	16
Table 3	Flammability Information Of Agents	17

1.0 Introduction

1.1 Operation And Maintenance Manual

This Operation And Maintenance (O & M) Manual contains the information required in order to install, operate and maintain the Ohmeda Universal PAC.

Requests for servicing facilities, advice or assistance must be addressed to a local Ohmeda Field Operations Unit.

Additional copies of this manual, quoting Ohmeda Universal PAC O&M Manual Part No. 1101-0001-000 can be requested from a local Ohmeda Field Operations Unit.

It is recommended that all relevant documentation, including the O&M Manual and accompanying labels and/or inserts, is immediately available to all prospective operators.

1.2 Precautions

A number of **Warnings** ⚠ and **Cautions** ⚠ are used throughout this manual to draw attention to the possible hazards and/or adverse conditions which may occur if the information and instructions provided are not strictly observed.

Warnings are used to draw attention to a condition which can endanger either the patient or the operator. Cautions are used to draw attention to a condition which can result in damage to the equipment.

Special attention must be paid to each Warning and Caution as it appears in the manual.

1.3 User Responsibility

The performance of this Product conforms with the description thereof contained in this O & M Manual and accompanying labels and/or inserts when the Product is operated and maintained in accordance with the instructions provided. The Product must be checked periodically. A defective Product must not be used. Parts that are broken, missing, obviously worn, distorted or contaminated must be replaced immediately. Should such repair or replacement become necessary, Ohmeda recommends that a request for service advice is communicated to the nearest Ohmeda Field Operations Unit.

It is recommended that this Product, including any of its parts, is repaired by Ohmeda trained personnel in accordance with written instructions provided by Ohmeda. The Product must not be altered without the prior written approval of Ohmeda. The user of this Product shall have sole responsibility for any malfunction which results either from alteration by anyone other than Ohmeda trained personnel or from improper use, faulty maintenance, improper repair or damage.

1.4 Servicing Policy

⚠ **Warning: Only Technicians/Engineers trained and certificated by Ohmeda Steeton to repair and/or service the Ohmeda Universal PAC should attempt to repair and/or service it and it must be repaired and/or serviced in accordance with written instructions provided by Ohmeda.**

Servicing procedures for this Product must be performed by Ohmeda trained personnel in accordance with written instructions provided by Ohmeda.

Warranty repair and service procedures must be performed at an Authorized Ohmeda Service Center.

Do not use malfunctioning equipment.

If the equipment is to be transported to the nearest Authorized Ohmeda Service Center, drain the vaporizer, package it securely for protection in its original packaging, if possible, and ship it prepaid. Enclose the following items as applicable:

1. A letter describing in detail any difficulties experienced with the equipment.
2. Warranty information, such as a copy of the invoice or other applicable documentation.
3. Purchase order number to cover repair of equipment not under warranty.
4. Ship to and bill to information.
5. The name and telephone number of the person to contact for functional details.

2.0 Description

⚠ **Warning: This manual and all its associated documentation must be studied thoroughly before any attempt is made to operate or maintain any part of the Ohmeda Universal PAC. Failure to do so may result in patient injury.**

The Universal Draw-Over Vaporizer has been specially developed for military battlefield use only. It is designed to be used over the range of minute volumes normally encountered in draw-over anesthesia with intermittent flows, with ambient air or in non-rebreathing demand systems. A non-return valve is incorporated to minimize the possibility of rebreathing across the vaporizer.

⚠ **Warning: The Ohmeda Universal PAC system is intended for use only in military battlefield situations where conventional closed, semi-closed continuous low flow or other more sophisticated anesthesia systems are not available. Failure to utilize a conventional anesthesia system when available significantly increases the risk of patient injury.**

The vaporizer is calibrated in the simulated spontaneous breathing mode. When the vaporizer is used under assisted ventilation conditions with a self-inflating bag it has a negligible affect on the concentrations delivered, as illustrated on Fig. 3, 4 and 5.

The vaporizer is not normally suitable for use in the continuous fresh gas circuit of either a rebreathing or a partial rebreathing system.

⚠ **Warning: Do not use the vaporizer in either closed or semi-closed anesthesia circuits.**

The vaporizer is temperature compensated, low resistance, non-spill and is primarily designed for use with either Isoflurane or Halothane.

The dial disc is reversible and is calibrated on one side for Isoflurane and on the other side for Halothane. When the dial disc is removed, the main dial located below the dial disc can be used for either Diethylether or Enflurane and, if the disc is mislaid, for Isoflurane and Halothane with delivery concentrations as shown in Table 1. The drain screw must be used as the tool for removing the dial disc.

⚠ **Warning: Ensure that the correct dial disc is fitted if either Isoflurane or Halothane is used. With other agents ensure that the vaporizer is clearly marked with the service drug.**

⚠ **Warning: Do not immerse the vaporizer in any liquid including water.**

⚠ **Warning: Do not sterilize the vaporizer.**

⚠ **Warning: Due to its physical properties Diethylether must not be used in conditions where the temperature exceeds 34 deg. C (93 deg. F).**

⚠ **Warning: The use of supplemental oxygen is strongly recommended whenever the Ohmeda Universal PAC is used. Failure to use supplemental oxygen may cause Hypoxemia, especially during spontaneous breathing or controlled ventilation.**

⚠ **Warning: Potentially hazardous excessive concentrations of anesthetic agent may occur at temperatures above 35 deg. C (95 deg. F).**

3.0 Specification

Nominal Working Temperature	18 to 35 deg. C (65 to 95 deg. F)
Resistance to Inhalation	1 cm wg. at 30 liters/minute
Liquid Capacity	The amount of anesthetic required to fully charge the vaporizer is 85 milliliters The amount of anesthetic retained by the wick system is 13 milliliters
Weight and Dimensions	Weight 2.3 kg (5 lbs) Height 190 mm (7 1/2 in.) Depth 130 mm (5 1/8 in.) Width 95 mm (3 3/4 in.)
Inlet/Outlet Connections	22 mm Tapered Connector

⚠ **Warning: Do not modify, tamper with or disassemble the vaporizer because of the danger of damaging the unit and/or altering the accuracy of graduation.**

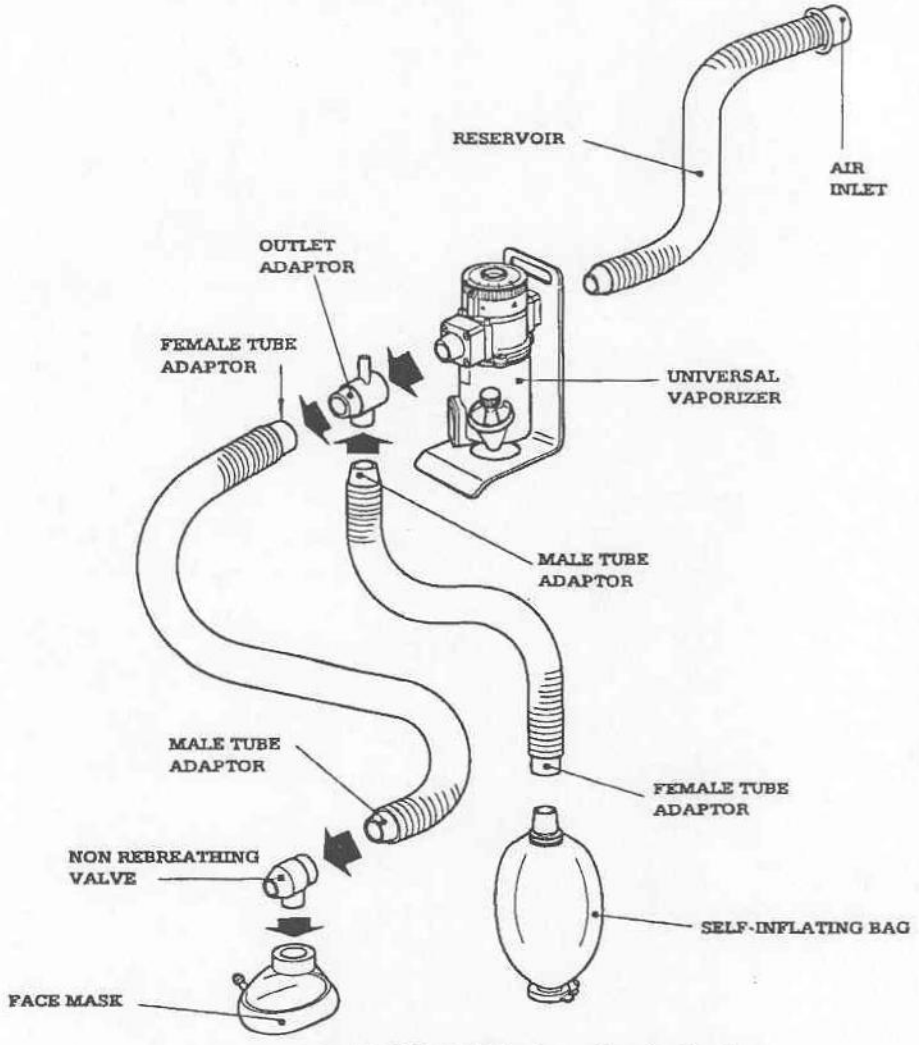

Fig. 1 PAC Portable Anesthesia System

4.0 Principle Of Operation

4.1 Description

Air Only	Air is drawn through the reservoir inlet.
Assisted Ventilation	Assisted ventilation is achieved by the self-inflating bag which is in circuit between the vaporizer and the patient. When the patient exhales, a non-rebreathing valve fitted to the face mask opens to atmosphere to prevent exhaled gases from flowing into the self-inflating bag.
Supplementary Oxygen	A nipple is provided on the vaporizer inlet for connecting supplementary oxygen supplies.

Use with various agents is as follows:

Isoflurane and Halothane	Dual sided calibrated from 0.5 to 5% for each agent.
Diethylether or Enflurane	When the dial disc is removed, the vaporizer delivers the nominal concentrations detailed in Section 5.2 Table 1 at the scale settings indicated.

⚠ **Warning: Diethylether is a flammable agent.**

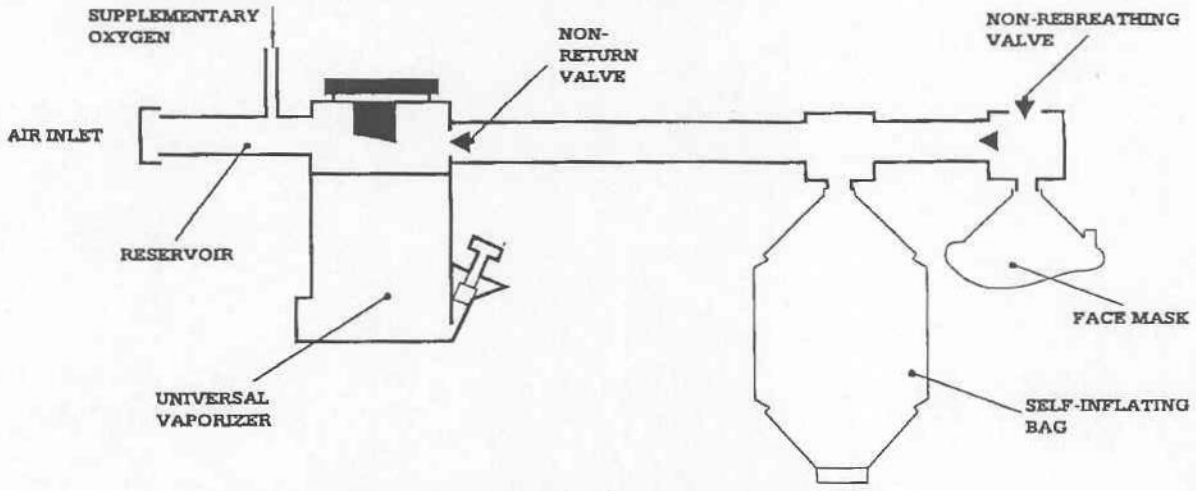

Fig. 2 PAC Portable Anesthesia System - Schematic

4.2 Duration Of Use

The rate of consumption of anesthetic depends primarily on flowrate and vapour output concentration. As an approximate working figure, 1 milliliter of liquid anesthetic is required to produce 200 milliliters of vapour.

The rate of evaporation of anesthetic agent may, with caution, be used both as an approximate method of checking that the delivered output is not grossly in error, and as a means of estimating how frequently the vaporizer is likely to need refilling.

The approximate hourly consumption of anesthetic agents can be expressed as 3 x % x F where % represents the setting of the vaporizer output percentage and F represents the throughput flowrate in liters/minute.

Example: If a vaporizer is set to deliver 2% at 6 liters/minute total throughput gas flowrate, the approximate rate of consumption = 3 x 2 x 6 = 36 milliliters/hour.

It must be appreciated that the figures are intended for clinical guidance only and are approximate. The figures vary depending upon the type of anesthetic agent employed and can be grossly in error if the vaporizer drain port is not fully closed.

At a mid-scale setting with a minute volume of 6.0 liters the approximate duration of free liquid charge is as follows:

Halothane	100 minutes
Isoflurane	100 minutes

Diethylether	30 minutes
Enflurane	110 minutes

5.0 Performance

5.1 Performance Curves

Performance curves have been established under the following conditions:

1. Performance Curve under simulated assisted ventilation conditions using an Ohmeda V 5A ventilator at 16 cycles/minute, square wave breathing pattern with air at 22 deg. C.

2. Performance Curve under simulated spontaneous breathing conditions of 16 cycles/minute, sine wave breathing pattern with air at 22 deg. C.

For practical purposes the curves referred to in 1 and 2 above are identical and are illustrated in Fig. 3, 4 and 5.

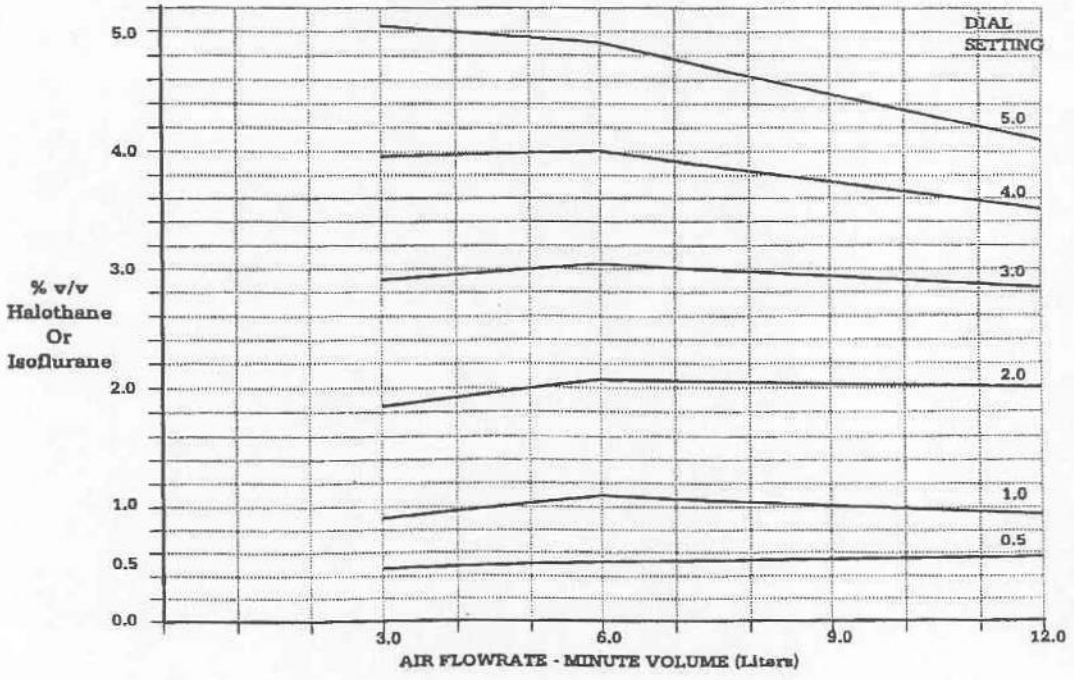

Fig. 3 Halothane And Isoflurane Performance Curve

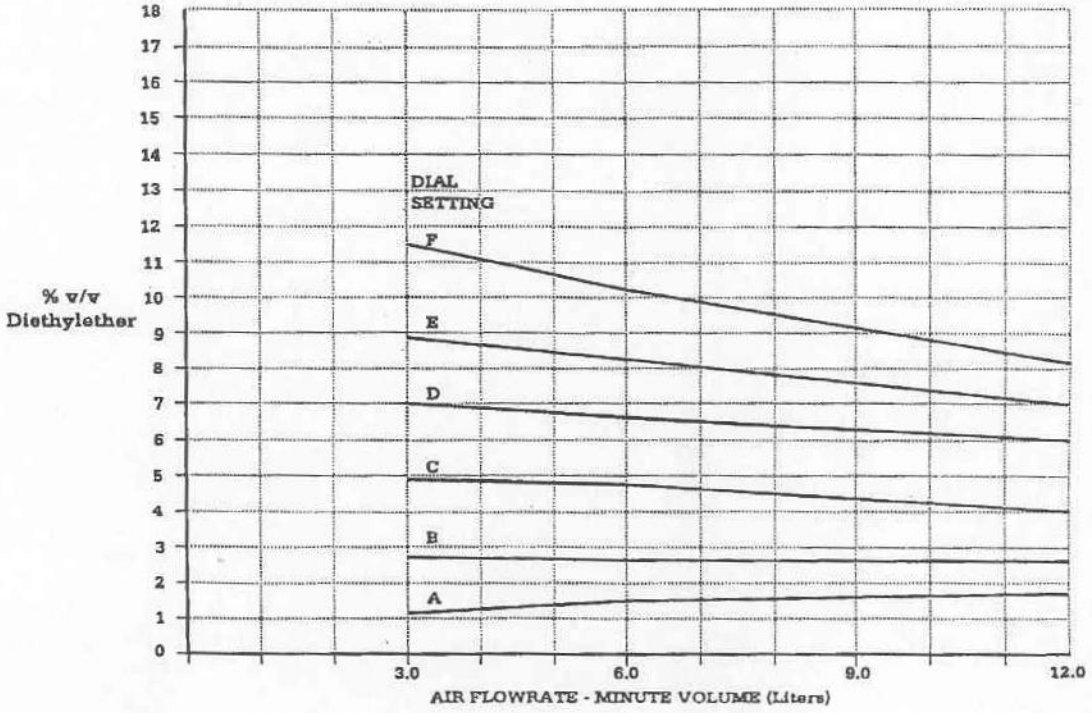

Fig. 4 Diethylether Performance Curve

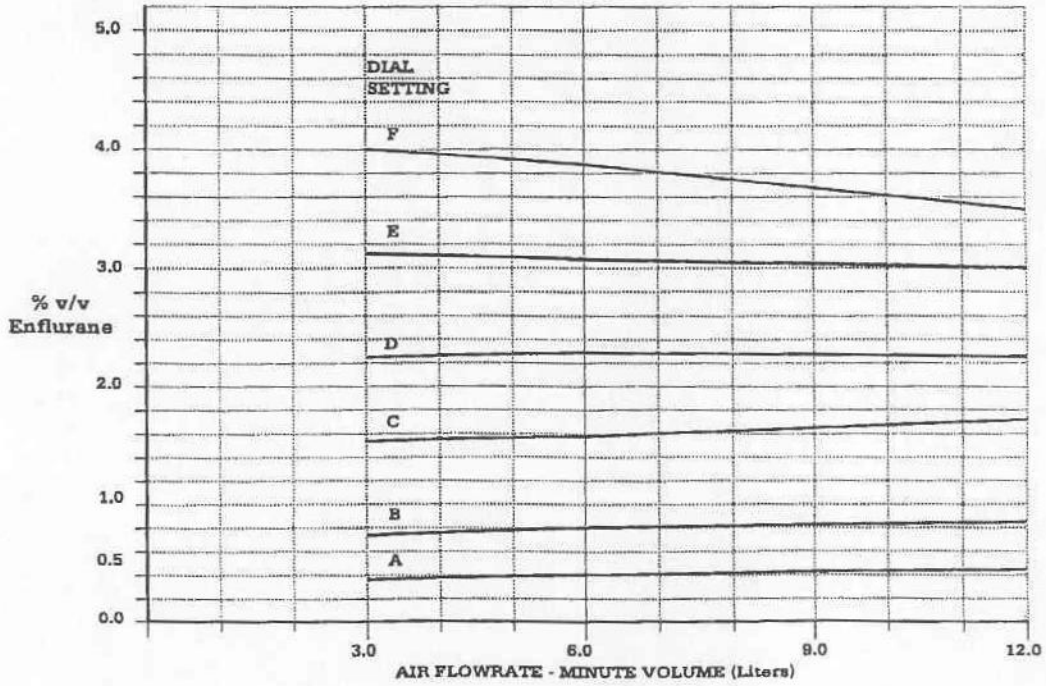

Fig. 5 Enflurane Performance Curve

5.2 Nominal Performance With Other Agents

Calibration data for the main dial have been established under the following conditions:

1. Performance under simulated assisted ventilation conditions using an Ohmeda V5A ventilator at 16 cycles/minute, square wave breathing pattern with 6 litres/minute volume of air at 22 deg. C (72 deg. F).

2. Performance under simulated spontaneous breathing conditions of 16 cycles/minute, sine wave breathing pattern with 6 litres/minute volume of air at 22 deg. C (72 deg. F).

For practical purposes the nominal calibrations referred to in 1 and 2 above are identical and are detailed in Table 1.

Note: Table 1 is a copy of the label which is affixed to the Ohmeda Universal PAC.

Drug Type / Dial Setting	Nominal Calibrations			
	% v/v Diethylether	% v/v Enflurane	% v/v Halothane	% v/v Isoflurane
A	1.55	0.50	0.50	0.60
B	2.70	0.90	1.00	1.20
C	4.80	1.70	2.00	2.15
D	6.65	2.40	3.00	3.10
E	8.20	3.10	4.00	4.00
F	10.10	3.85	5.00	5.00

Intermediate concentrations can be obtained by setting the knob scale between the settings shown.

Table 1 Nominal Performance With Other Agents

5.3 Effects Of Temperature On Performance

Information is provided for two conditions of use, as follows:

1. Performance Curve under simulated assisted ventilation conditions using an Ohmeda V5A ventilator at 16 cycles/minute, square wave breathing pattern with 6 liters/minute volume of air at 22 deg. C.

2. Performance Curve under simulated spontaneous breathing conditions of 16 cycles/minute, sine wave breathing pattern with 6 liters/minute volume of air at 22 deg. C.

For practical purposes the curves referred to in 1 and 2 above are identical and are illustrated in Fig. 6, 7 and 8.

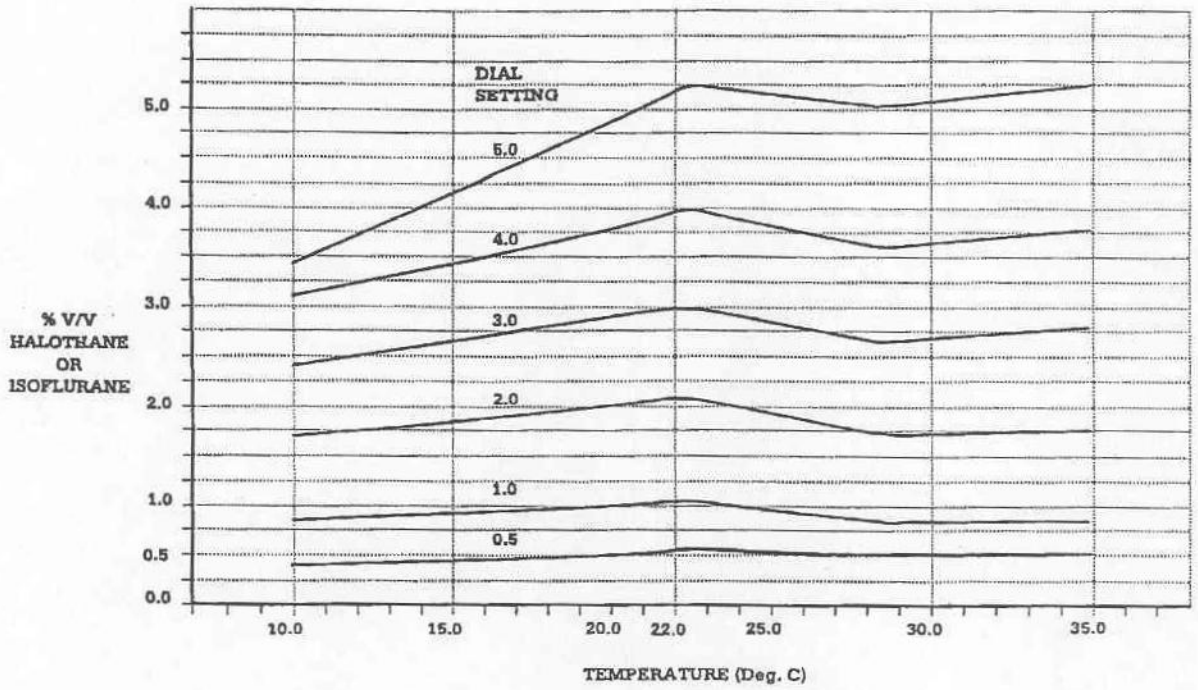

Fig. 6 Effect Of Temperature On Performance - Halothane And Isoflurane

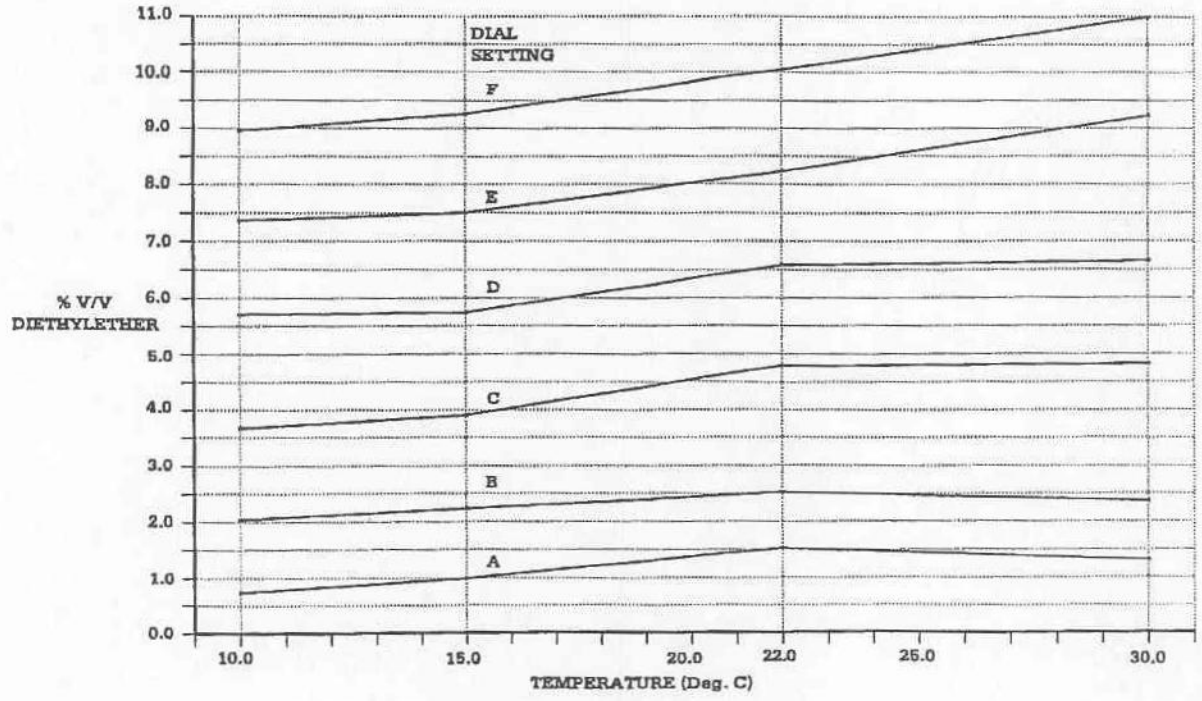

Fig. 7 Effect Of Temperature On Performance - Diethylether

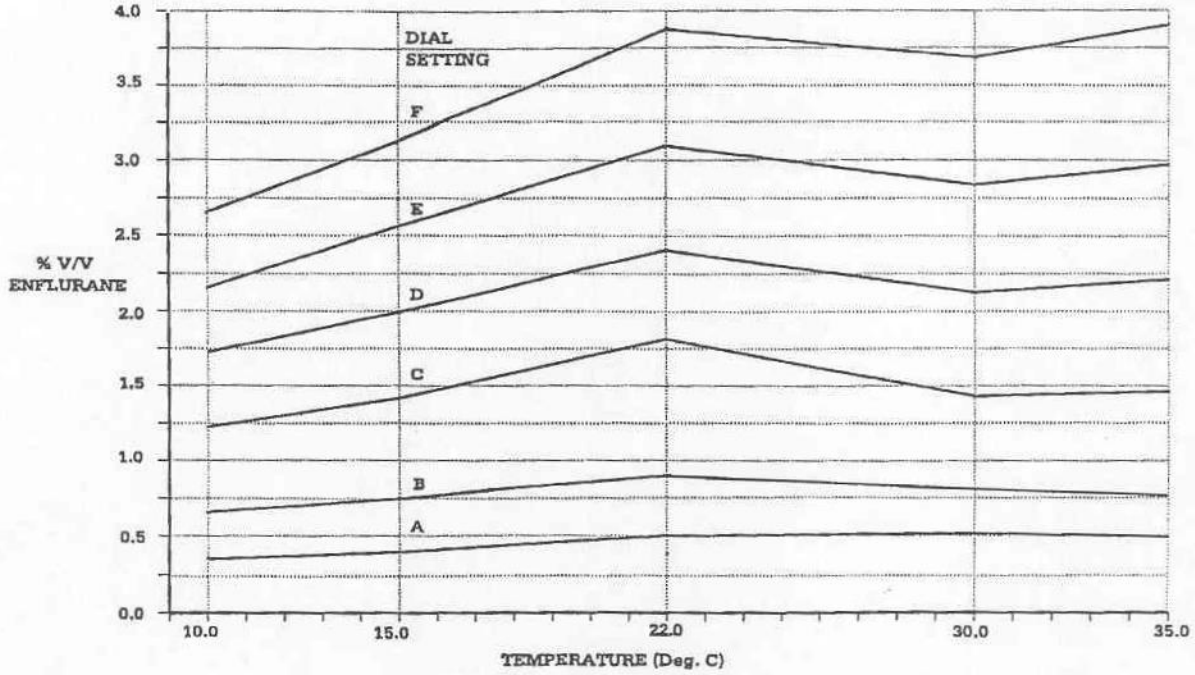

Fig. 8 Effect Of Temperature On Performance - Enflurane

5.4 Effects Of Variables

A Temperature

The vaporizer is temperature compensated and the effects of variations in temperature are normally negligible at commonly used combinations of dial setting and ambient temperature.

A safety feature is incorporated in the temperature compensating valve to help to prevent the valve from responding to temperatures below the range of approximately 12 to 15 deg. C (54 to 59 deg. F). If the vaporizer temperature is lower than approximately 12 to 15 deg. C (54 to 59 deg. F) then the output can be expected to be higher than that indicated on the dial.

At temperatures above the range shown on the performance curves, the vaporizer output may be unpredictably high.

⚠ **Warning: Potentially hazardous excessive concentrations of anesthetic agent may occur at temperatures above 35 deg. C (95 deg. F).**

To help to avoid inaccuracies due to extreme temperatures the vaporizer should be allowed to attain a temperature in the range shown on the performance curve prior to use.

Several factors may affect the time required for the vaporizer to attain the required temperature but a minimum of 1 hour must be allowed to enable the vaporizer and agent temperature to stabilize.

B Pressure

Vaporizers are graduated in % v/v at 760 mm Hg. If the ambient pressure changes the % v/v changes so that at an ambient pressure P mm Hg the delivered percentage (D % v/v) =

Equation 1 $D = \frac{\% \times 760}{P}$ where % is the nominal setting of the vaporizer

It is generally accepted that the depth of anesthesia depends on the inspired partial pressure of agent and not the concentration by volume of agent.

To obtain a consistent depth of anesthesia when gross changes of barometric pressure occur, it is necessary to change the % v/v in inverse proportion to the barometric pressure.

The vaporizer automatically makes this change in the % v/v, therefore for practical clinical purposes the effects of the barometric pressure can be ignored.

C Back Pressure

Fluctuating back pressure may be imposed on the vaporizer by downstream components and assisted or controlled ventilation to the patient. This fluctuating back pressure can affect the vaporizer and increase the concentration by intermittently altering the pressures and hence the flow distribution within the vaporizer.

6.0 Checks Before Use

If the system is in continuous use it is recommended that the following brief checks are performed daily. If the system is in not continuous use it is recommended that the checks are performed each time the system is intended to be used. The checks can help to indicate that the system is in good working order.

6.1 Visual Checks

1. Inspect the flexible hoses illustrated on Fig. 1 for any damage such as cuts and/or splits. Replace the complete hose assembly if a hose is damaged.
2. Examine the breathing assembly for damage.
3. Check all components for security of attachment.
4. Check the liquid level in the vaporizer and refill as necessary.
5. Visually examine the vaporizer for any signs of damage and, if any damage is found, do not use the vaporizer. Contact an Authorized Ohmeda Service Center, request a replacement vaporizer and return the damaged vaporizer to the Authorized Ohmeda Service Center.

6.2 Leak Tests - Internal

1. Turn ON the vaporizer.
2. Squeeze the self-inflating bag and hold it in this condition.
3. Cap the air inlet and the oxygen nipple and then release the self-inflating bag.
4. If the bag does not then re-inflate there are no significant leaks.

6.3 Leak Tests - External

1. Cap the face mask port and the expiratory valve port.
2. Attempt to squeeze the self-inflating bag.
3. If the bag cannot be totally squeezed then there are no significant external leaks.

Most simple leaks can be rectified by tightening the appropriate connector or screws. Leaks at low pressure tapered gas connectors can usually be rectified by pushing the components together accompanied by a wringing action.

Repairs must only be performed at an Authorized Ohmeda Service Center.

⚠ **Warning: Check the breathing and ventilation circuits before use.**

7.0 Operation

Air flow through the vaporizer is governed by the rotary, concentration setting dial which is directly linked to an underlying rotary valve.

The dial disc is reversible and is calibrated on one side for Isoflurane and on the other side for Halothane. When the dial disc is removed, the main dial located below the dial disc can be used for either Isoflurane, Halothane, Diethylether or Enflurane with nominal delivery concentrations as shown in Table 1.

With the control dial set to the OFF position, the rotary valve covers and seals the vaporizing chamber inlet and outlet tubes. Air is free to pass from the inlet to the outlet via a bypass, as illustrated on Fig. 9. As the control dial is moved away from the OFF position the underlying rotary valve is moved and opens the inlet and outlet ports to the vaporizing chamber so that some of the main airstream can pass through the vaporizing chamber.

The bypass gap is formed by the top of the rotary valve and the sloping face inside the top cover so that as the valve is rotated the gap is reduced.

When the bypass is reduced greater proportions of the main airstream are directed into the vaporizing chamber with a corresponding increase in the percentage of vapour at the outlet. The operation is summarized as follows:

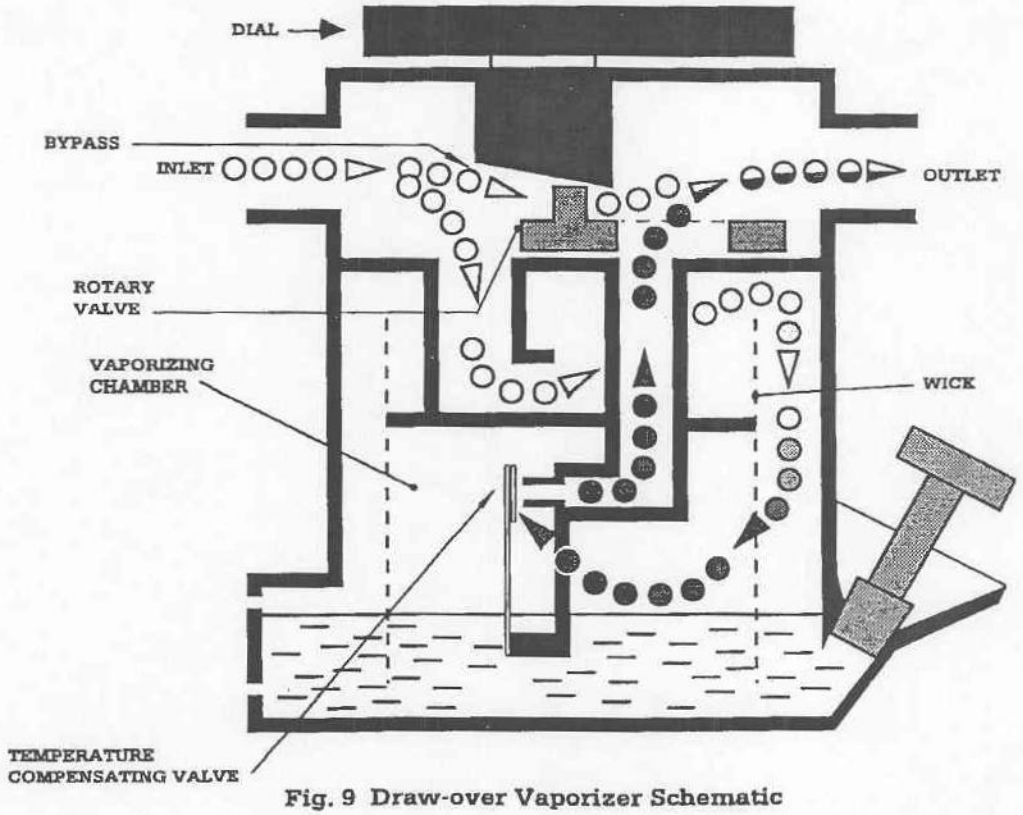

Fig. 9 Draw-over Vaporizer Schematic

1. The patient draws air through the vaporizer.

2. Depending on the dial setting some of the air flows through the vaporizing chamber where it picks up the anesthetic agent as it passes over the absorbent wicks. The remaining air passes through the bypass to the outlet.

3. As the agent is evaporated the temperature decreases and the vapour pressure also decreases.

4. A temperature compensating valve is incorporated to compensate for the cooling effect and also for changes in ambient temperature. The valve senses any change in temperature and automatically adjusts flows in the vaporizing chamber to compensate for any change in temperature.

The vaporizing chamber is arranged so that the free liquid cannot pour into the breathing circuit if the vaporizer is accidentally inverted.

This is achieved by passing the air to the vaporizing chamber down through a pipe to a dividing plate. To leave the vaporizing chamber the air passes through the temperature compensating valve and up through a pipe to the outlet.

The pipes are so arranged that the liquid agent is confined to the vaporizing chamber even if the vaporizer is laid on its side or inverted.

8.0 Operating Instructions

8.1 General

The Universal Draw-Over Vaporizer is a precision instrument and it must be handled with care at all times.

Important Note: It is strongly recommended that oximeters, capnography and/or other respiratory monitoring devices are used when available.

Observe all instructions included on the vaporizer labels.

⚠ **Caution: Turn the vaporizer OFF when it is not in use.**

If the vaporizer is accidentally tilted during use it can be safely returned to its upright position without interrupting the anesthetic procedure.

The free liquid level must be checked periodically and the vaporizer must be refilled at appropriate intervals. The vaporizer functions satisfactorily as long as liquid is above the minimum ▽ mark and the wicks are saturated.

⚠ **Warning: Turn the dial to the OFF position before filling.**

If a ventilator is in use the vaporizer must be on the inlet side of the ventilator with the ventilator between the vaporizer and the patient. Make certain that the functioning of the ventilator is not impaired by the vaporizer non-return valve.

Where unusually low minute volumes occur, with infants for example, it is recommended that special care is exercised in patient management because the accuracy of graduation and the functioning of the non-return valve may be affected. Refer to the Performance Curves.

⚠ **Caution: During external cleaning procedures, cleaning agents must not be allowed to enter the gas inlet or outlet ports and must not be allowed to accumulate either in the vaporizer filler or around the control dial.**

⚠ **Warning: If the vaporizer is dropped or damaged it must be taken out of service and the calibration must be checked at an Authorized Ohmeda Service Center.**

8.2 Filling And Draining

⚠ **Caution: The vaporizer must only be filled with the agents for which it is designed. Details of the agents are shown in Table 1.**

The vaporizer should be filled and used in an upright position. Small deviations from the upright position during use do not affect either the output or the safety of the vaporizer, but because the agent depth is shallow in relation to the diameter of the vaporizing chamber, more frequent checks of the agent level must be carried out when small deviations from the upright position occur in order to avoid obtaining a misleading impression of the amount of agent in the vaporizer.

A Filling

1. Turn the dial to OFF and remove the filler plug.
2. Ensure that the drain cap is closed.
3. Verify that all labels and dial specifications coincide.
4. Verify that the agent is the agent specified on both the label and the dial.
5. Observe the agent level through the sight glass and pour agent slowly into filler opening.

Note: If the vaporizer is dry the level decreases slightly as the wicks absorb the agent.

6. Replace the filler plug and tighten it to minimize the possibility of leaks.

B Draining

Partially unscrew the drain cap located underneath the vaporizer and drain into a properly marked container.

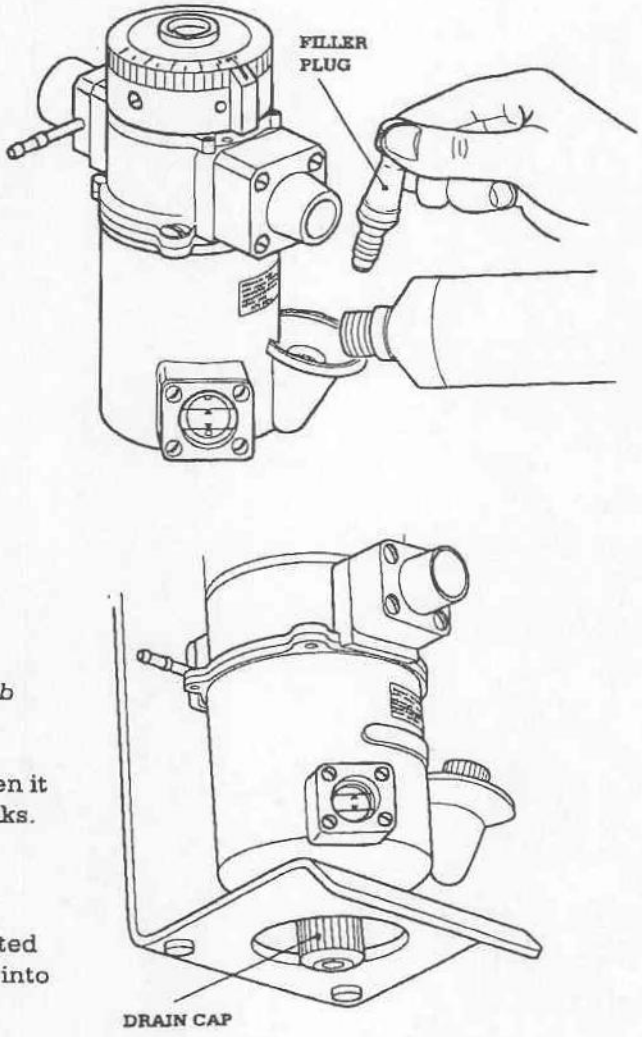

Fig. 10 Filling And Draining

C Packing

Prior to packing and transit, it is advisable to drain the vaporizer and then dry out any remaining drops of free liquid by passing gas through the vaporizer for approximately 15 minutes with the dial at maximum setting.

⚠ **Warning: Appropriate measures must be taken to handle exhaust gases and spillage.**

If Diethylether is the service agent, continue drying out until the liquid contained in the wicks has evaporated as described in 8.2 E.

D Cleaning

⚠ **Warning: Do not put water or any other solvent in a vaporizer. A vaporizer must be filled with the specified anaesthetic agent only.**

Clean the exterior of the vaporizer with a damp cloth.

⚠ **Caution: Never allow cleaning agents to accumulate in the filler, the gas inlet and outlet ports or around the control dial.**

E Changing To A Specific Agent

1. Fully drain the vaporizer and retighten the drain cap.
2. Dry out the wicks by passing air through the vaporizer until all the agent has evaporated, as follows:
   a) Connect a self-inflating bag or bellows to the vaporizer inlet using appropriate non-return valves.
   b) Operate at approximately 750 milliliters tidal volume and 24 cycles/minute.
   c) Continue the process until vapour cannot be detected at the vaporizer outlet.
   d) The process typically lasts approximately 15 minutes with Halothane or Isoflurane, but the time occupied may be shorter with Diethylether or longer with Enflurane.

⚠ **Warning: Appropriate measures must be taken to handle exhaust gases and spillage.**

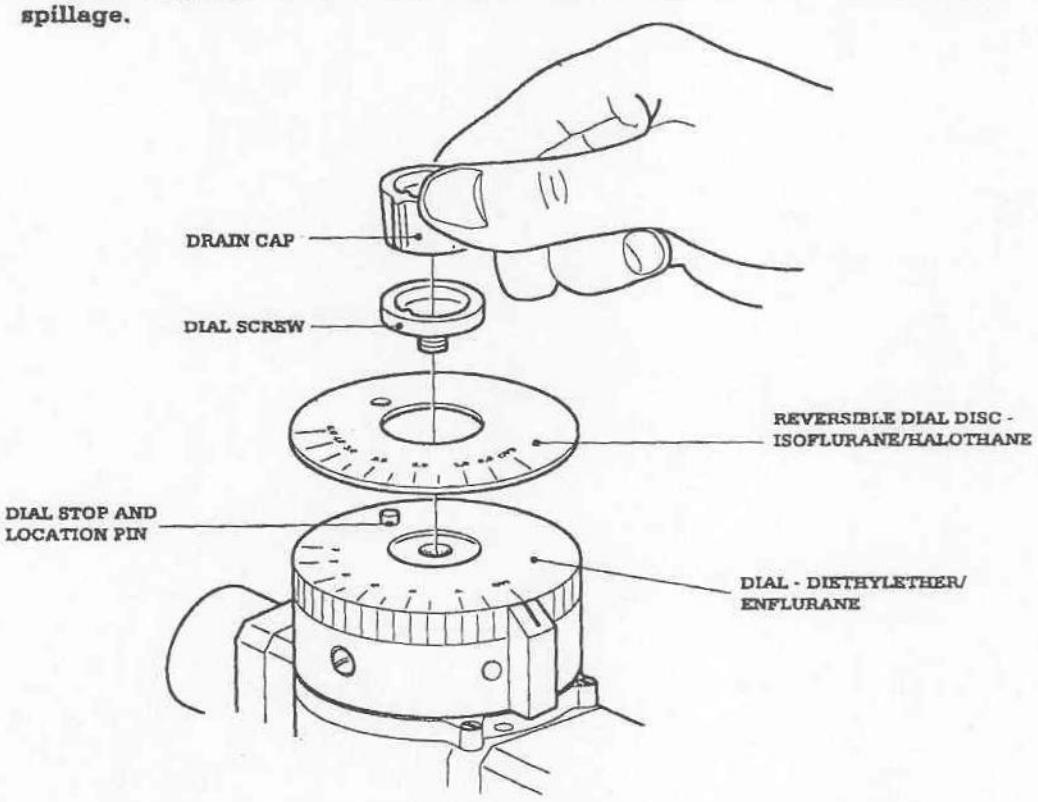

Fig. 11 Changing The Control Dial

3. Remove the drain cap and use it as a tool to remove the dial screw.

4. Select the disc or dial as required, refit and secure the dial screw.

5. Refit the drain cap and tighten it.

6. Label the vaporizer accordingly and fill the vaporizer with the appropriate agent.

8.3 Minimum Alveolar Concentration (M.A.C.)

The adjacent MAC Table is provided for reference only. However it is expected that sound clinical judgement on a case-to-case basis is followed for each use of this equipment.

M.A.C. = Minimum Alveolar Concentration (Vol. per %) at 1 ATM, which produces immobility in 50% of subjects exposed to noxious stimuli.

Agent Identification	Potency M.A.C. Value Volume %
1. Diethylether	1.92
2. Halothane	0.76
3. Enflurane	1.68
4. Isoflurane	1.15

Table 2 Minimum Alveolar Concentration (M.A.C.)

9.0 Factors Relating To Individual Anesthetics

9.1 General

Some brands of agent may contain dyes which are used for identification purposes. It is desirable to remove accumulated dye by draining, internal rinsing with a clear agent and drying out the wicks before using the vaporizer with another agent.

9.2 Isoflurane

The Isoflurane dial disc is graduated from 0.5% to 5.0%.

9.3 Halothane

The Halothane dial disc is similar to the Isoflurane dial disc and the same general performance characteristics apply.

Halothane contains Thymol as a stabilizing agent. If Halothane is used for prolonged periods of time it is desirable to drain the vaporizer when the liquid level is low and discard the liquid.

Discarding the liquid at intervals of approximately two weeks prevents excessive accumulation of the stabilizer.

9.4 Diethylether

⚠ **Warning: Diethylether is an extremely flammable agent and appropriate safety precautions must be taken to minimize the possibility of fire or explosion. Extreme care must be taken during its application**

Limits of Flammability in Oxygen or Air (Vol. %)

Agent Type	Lower Limit in		Upper Limit in		Comments
	Oxygen	Air	Oxygen	Air	
Diethylether	2.1	1.8	82.0	36.0	Must be considered flammable under most clinical conditions

Table 3 Flammability Information Diethylether

The Diethylether scale graduations are denoted with letters and must be used in conjunction with Table 1 which shows the approximate delivered concentration for each graduation.

During anesthesia Diethylether concentrations tend to be high and consequently the rate of liquid consumption is high therefore it is necessary to check the liquid level frequently.

To help to reduce the risk of flammability it is necessary to drain the vaporizer of Diethylether and dry it prior to storage or transportation.

9.5 Enflurane

The Enflurane scale graduations are denoted with letters and must be used in conjunction with Table 1 which shows the approximate delivered concentration for each graduation.

10.0 Servicing

10.1 General

⚠ **Caution: Do not have the vaporizer serviced by anyone other than an Authorized Ohmeda Service Center.**

Taking into account the the amount of time that vaporizer is in use it is recommended that a complete service is performed on the vaporizer at an Authorized Ohmeda Service Center at the following intervals:

Amount Of Use	Recommended Interval Between Full Service
Constant daily use for several hours a day	Every year
Intermittent use, for example, emergency clinics etc.	Every two/three years
Occasional use when the vaporizer is fully dried out between periods of use	Every five years

10.2 Scope

The vaporizer service comprises the following procedures:

1. Complete disassembly of components
2. Thorough cleaning
3. Inspection for damage and wear
4. Renewal of wicks, seals and damaged or worn components
5. Lubrication where necessary
6. Calibration which consists of checks of the delivered concentration under closely defined conditions at several different temperatures and regraduation or adjustment where necessary.

Ohmeda

Manufactured by
Ohmeda,
Station Road, Steeton,
West Yorkshire, BD20 6RB,
England, U.K.
Telephone 0535 656016
Telex 51631 Cypkly G
Rapifax 0535 653690

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